K042534

MAY 10 2005

510(k) Summary

As Required by 21 section 807.92 (c)

1-Submitter Name: Marina Medical

2-Address: 2761 N. 29th Avenue
Hollywood, FL 33020

3-Phone: (954) 924-4418
4-Fax: (954) 924-4419
5-Contact Person: Anthony Zinnanti

6-Date summary prepared: March 23rd, 2005 by Jay Mansour- Mansour Consulting LLC

7-Device Trade or Proprietary Name: MARINA MEDICAL FINGER PROTECTOR

8-Device Common or usual name: SURGEON'S FINGER PROTECTOR

9-Device Classification Name: NEEDLE ACCESSORY

10-Substantial Equivalency is claimed against the following device:
DIGICAP, cleared via K012199 for HUMANA USA, INC

11-Description of the Device:

This device is a sterile single use protective finger guard worn in conjunction with surgeon's glove.

12-Intended use of the device:

This device is a protective finger guard accessory to the surgeon's glove.

(a) intended to provide needlestick and suture/scalpel protection during a variety of surgical procedures. It is a protective finger guard accessory to the surgeon's glove. It is used on the finger or thumb of the non-dominant hand usually used to retract, stabilize, compress, and position tissue during surgical procedures.

(b) Facilitate suture handling and placement.

13-Safety and Effectiveness of the device:

This device is safe and effective as the other predicate device cited above.
This is better expressed in the tabulated comparison (Paragraph 14 below)

14-Summary comparing technological characteristics with other predicate device:

Please find below a tabulated comparison supporting that this device is substantially equivalent to other medical devices in commercial distribution. Also, Equivalency overview chart path is attached.

Summary - PAGE 7-REVISED

FDA file reference number	510k # K012199
TECHNOLOGICAL CHARACTERISTICS	**Comparison result**
Indications for use	Identical
Target population	Identical
Design	Identical
Materials	Identical
Performance	Identical
Sterility	Identical
Biocompatibility	Identical
Mechanical safety	Identical
Chemical safety	Identical
Anatomical sites	Identical
Human factors	Identical
Energy used and/or delivered	Not applicable
Compatibility with environment and other devices	Identical
Where used	Identical
Standards met	Identical
Electrical safety	Not applicable
Thermal safety	Not applicable
Radiation safety	Not applicable

SUMMARY - PAGE 8 - REVISED

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 10 2005

Marina Medical Instruments, Incorporated
C/O Mr. Jay Mansour
President
Mansour Consulting LLC
1308 Morningside Park Drive
Alpharetta, California 30022

Re: K042534
Trade/Device Name: Marina Medical Finger Protector
Regulation Number: 878.4460
Regulation Name: Surgeon's Glove
Regulatory Class: I
Product Code: KGO
Dated: April 27, 2005
Received: April 28, 2005

Dear Mr. Mansour:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K042534

Device Name: MARINA MEDICAL FINGER PROTECTOR

Indications For Use:

This device is a protective finger guard accessory to the surgeon's glove.

(a) intended to provide needlestick and suture/scalpel protection during a variety of surgical procedures. It is a protective finger guard accessory to the surgeon's glove. It is used on the finger or thumb of the non-dominant hand usually used to retract, stabilize, compress, and position tissue during surgical procedures.

(b) Facilitate suture handling and placement.

Prescription Use ✔ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
510(k) Number: K042534

PAGE 11 - REVISED